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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,039	09/22/2005	Clifford J. Steer	P0093AUTL00	8552

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EXAMINER	
CLARK, SARA E	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
11/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/532,039	STEER ET AL.	
	Examiner	Art Unit	
	SARA E. CLARK	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/23/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

Receipt is acknowledged of Applicants' Amendments and Remarks, filed 6/29/2009.

Claims 1 and 8 have been amended and incorporate no new matter.

No new claims have been added.

Thus, claims 1-17 now represent all claims currently pending and under consideration.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement (IDS) submitted on 7/23/2009 was filed after the mailing date of the first Office Action on 3/31/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

WITHDRAWN REJECTIONS

Double Patenting Rejections

Due to the abandonment of co-pending application 10/246,025 on 5/11/2009, the rejection of claims 1 and 8 as unpatentable over claim 30 of copending application 10/246,025 is withdrawn.

Applicant's arguments, see p. 7, filed 6/29/2009, with respect to the rejection of claims 1, 3-5, 8, and 10-12 as unpatentable over claims 8-11 of co-owned US Pat. 6,544,972 have been fully considered and are persuasive. Therefore, this rejection has been withdrawn.

MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Action dated 3/31/2009, on the ground that the references cited therein continue to read on the limitations of the amended claims.

Rejections under 35 USC §102(b)

Claims 1-17 stand rejected under 35 USC §102(b) as anticipated by Steer et al. (WO99/15179).

RESPONSE TO ARGUMENTS

In response to applicant's argument that WO99/15179 lacks an express recitation of each and every element recited by the claims, in particular methods of treating a nervous system injury "wherein the nervous system injury is associated with hemorrhage," it is noted that the claimed methods are implicitly disclosed and inherently achieved by those taught by the reference.

Specifically, WO99/15179 discloses methods of limiting apoptosis (cell death) in a cell population by contacting such cells with the claimed compounds, ursodeoxycholic acid (UDCA) or its taurine or glycine conjugates, glycoursodeoxycholic acid (GUDCA), and tauroursodeoxycholic acid (TUDCA) (abstract; p. 1, line 16). The reference defines the term "limiting" apoptosis as preventing, reducing, suppressing, and/or inhibiting the

occurrence of apoptosis, which can be associated with a variety of diseases (p. 11, lines 16-19). In particular, a method is disclosed for inhibiting apoptosis associated with a nonliver disease *in vivo*, such as "a cardio/cerebrovascular disease (e.g. stroke, myocardial infarction and the like)" (p. 4, lines 8-13).

The reference also teaches that "[n]eurons may also die from apoptosis, particularly in oxygen-deprived brains. When brain ischemia was induced in laboratory animals by temporarily cutting the blood flow to the brain, several features of apoptosis were found in dying neurons. Preliminary results in a rat model indicate an improvement in mitochondria viability following a stroke injury in rats treated with tauroursodeoxy-cholic acid (TUDC). As compared to control animals, pretreatment with TUDC decreased the area of stroke damage by up to about 50%. These results indicate that ursodeoxycholic acid and its conjugated derivatives may provide benefit in rescuing injured cells following stroke injury" (p. 16, lines 22-30).

The instant claims are drawn to methods of treating a patient having a nervous system injury by administering [the claimed compounds, UDCA, GUDCA, or TUDCA] "wherein the nervous system injury is associated with hemorrhage" (claims 1-5, 8-12, and 15-17) and "wherein the nervous system injury associated with hemorrhage comprises a hemorrhagic stroke" (claims 6-7 and 13-14). While the reference does not explicitly refer to "hemorrhage," the key nervous system injury resulting from either ischemic or hemorrhagic stroke is apoptosis (cell death). By disclosing methods of administering UDCA, GUDCA, or TUDCA to limit apoptosis associated with stroke, regardless of whether the stroke is of the ischemic or hemorrhagic variety, the reference

inherently discloses the treatment of a nervous system injury associated with hemorrhage or hemorrhagic stroke, namely, neural cell death.

In other words, the methods disclosed by WO99/15179 anticipate the claimed methods because administering UDCA, GUDCA, or TUDCA to limit or inhibit apoptosis associated with stroke comprises the same steps and inherently results in the treatment of a nervous system injury associated with hemorrhage or hemorrhagic stroke (i.e., neural cell death). See MPEP §2112.

CONCLUSION

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon - Thu, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARA E. CLARK/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612